Operator´s Manual
CS646 Cordless Battery Sealer

Qseal®·free

CONROY
Medical

Every effort has been made to ensure that the information in this document is correct, but we make no guarantee to this effect and would appreciate any observations regarding the contents of this document. We may make improvements and alterations to the instrument and these changes will be incorporated in new issues of this publication when practicable.

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Warnings and Cautions

The general safety information in the manual is for operating personnel. Specific notes, cautions and warnings are found throughout the manual where applicable. Please read the Operator's manual carefully before use.

Note! Identifies conditions that should be noted carefully.
Caution! Identifies conditions that could result in damage to the equipment.
Warning! Identifies conditions that could result in personal injury or loss of life.

Warning! Qseal-free must be used in compliance with all specifications and operational procedures listed in this manual.

Warning! When in use, Qseal-free must be used under the control of trained personnel.

Warning! Follow the operating instructions while operating Qseal-free.

Warning! Cables and accessories, others than those specified, may result in increased emission or decreased immunity of the equipment or system. Only accessories designed for use with Qseal-free should be used.

Warning! The equipment or system should not be used adjacent to other equipment. If adjacent use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Warning! If any of the components of Qseal-free are exposed to blood, they must be cleaned with an appropriate disinfectant solution.

Warning! Qseal-free is not intended for use in an oxygen rich environment.

Warning! Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warning! Qseal-free is not intended to be used with flammable anaesthetics and not intended for use in conjunction with flammable agents.

Warning! The device emits RF energy during seal procedure and movement of electrode.

Warning! The instrument must always be connected to a grounded outlet and with appropriate alternating current mains source, 100-130 or 230V~.

Warning! Disconnect the device from power source before performing any maintenance and cleaning procedure.

Warning! Do not modify this equipment without authorization of Conroy Medical or Conroy Medical authorized representative.

Caution! ELECTROMAGNETIC INTERFERENCE REGULATIONS
This equipment fulfils EN 60601-1-2:2015 Standards (Electromagnetic Compatibility). Nevertheless this equipment uses radio-frequency (RF) energy to generate heat while the tube is being sealed and can affect other Medical Electrical Equipment. If installation and use is not performed in accordance with this operator manual, it could cause interference with radio, television and instrument communications.

1. Scope

This chapter contains a description and specifications of the Qseal-free, a Portable Battery sealer from Conroy Medical AB.

1.1 Introduction

Qseal-free is a fully automatic system for sealing PVC or EVA tubes, especially for tubes in blood pack systems. Following the sealing procedure the tube is easily pulled apart, due to the distinct sealing pattern, with no damage to the blood inside the tubes. Segments are formed by inserting the tubing into the slot at the front of the sealing module to create a series of seals.

Qseal-free is comprised of a sealing module and battery module. It is complete with inbuilt sealing head and ready to operate. The front cover can be easily removed for cleaning. Different types or sizes of tubes can be used and the necessary sealing time is self-adjustable to suit the tubes that are being used.

Qseal-free works with radio frequency (RF) energy to generate heat for sealing. Users are requested to be cautious of potential electrical shocks or hazards while handling this sealer.

1.2 Performance and Specifications

The table below lists the physical specifications.

Parameter	Value/ Description
REF CS646:	Qseal-free, a complete sealing system, which includes Battery module, Sealing module, Charging station, Mains adapter, Plug kit and Operator's manual.
Type of PVC tube:	Different types and sizes of tubes up to 6.2 mm (0.24") outer diameter can be sealed due to a sophisticated sensing system, which automatically adapts sealing time.
Sealing capacity:	~500 seals/charge with PVC tubes up to 5 mm outer diameter at 20°C (68°F)
Contin. seal capacity:	20
Mode of operation:	Operation: 25%, Intermittens: 75%
Sealing time:	0.5 up to 3 sec. depending on tubing.
Intended purpose:	Intended for sealing tubes and bags in blood component sets. Qseal-free is intended to be used by trained medical professionals.
Input Power:	Mains adapter, single charger station 100-240 V ~ - 50/60 Hz
Output:	Mains adapter, single charge station 12 V ⎓ 28 W
RF Output:	80 W max. / 50 Ω / 40.680 MHz

Sealer Complete:	
Size (W x H x D)	200 x 47 x 166 mm (7.9 x 1.8 x 6.5 in)
Weight kg (lb):	663 g (1.46 lb)
Temperature:	Operating: 0 - 35°C (32 - 95°F) Storage: -20 - 70°C (-4 - 158°F)
Humidity:	Operating: 10 - 90% Rh (non condensing) Storage: 10 - 90% Rh (non condensing)
Altitude:	Operating: maximum 3000 meters (9842 feet) (70-106 kPa)
In compliance with:	- EN 60601-1: 2006, General Requirements for basic safety and essential performance. - EN 60601-1-2: 2007, 2014 Collateral standards for Electromagnetic Compatibility.
Electrical safety:	During charging Class II. ⧈ During use: Internal power supply. The Qseal-free is used in the same environment as medical equipment (hospitals and blood banks). It must be used by highly qualified personnel.
Patent pending.	
Manufacturer according to MDR:	Conroy Medical AB Haesthagsvaegen 14A SE-194 52 Upplands Vaesby SWEDEN

Table 1:

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The CS646 Qseal-free Portable Battery Sealer is intended for use in the electromagnetic environment specified below. The customer or the user of the CS646 Qseal-free should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emission CISPR 11	Group2	The CS646 Qseal-free must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emission CISPR 11	Class A	The CS646 Qseal-free is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Table 2:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS646 Qseal-free is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-free should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	6kV 8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	2kV Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	1kV 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% Uτ (> 95% dip in Uτ) for 0.5 cycle 40% Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles < 5% Uτ (> 95% dip in Uτ) for 5 sec	< 5% Uτ (> 95% dip in Uτ) for 0.5 cycle 40% Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles < 5% Uτ (> 95% dip in Uτ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE Uτ is the a.c. mains voltage prior to application of the test level.			

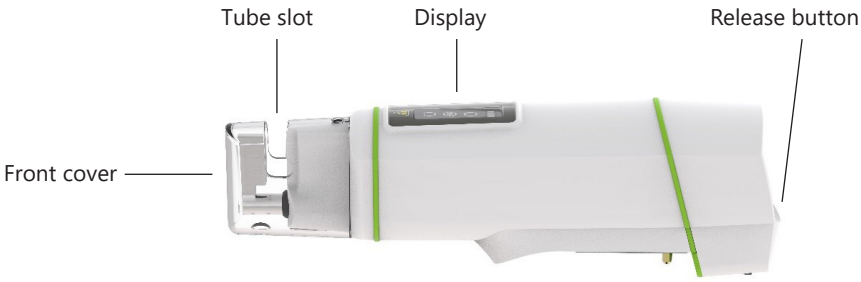
Table 4:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS646 Qseal-free is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-free should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the CS646 Qseal-free including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CS646 Qseal-free is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CS646 Qseal-free. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 6:

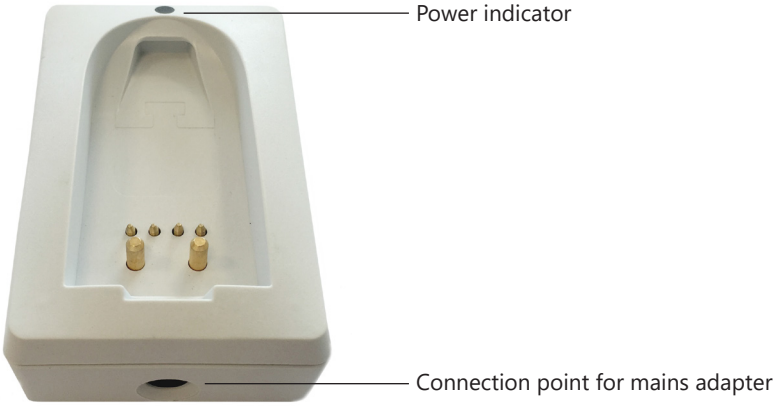
Recommended separation distance between portable and mobile RF communications equipment and the CS646 Qseal-free			
The CS646 Qseal-free is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS646 Qseal-free can help prevent electro-magnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS646 Qseal-free as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 1.17 √P	800 MHz to 2.5 GHz d = 2.33 √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer **NOTE 1** At 80MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Sealing module



Battery module

Single charger station



Mains adapter for single charger station

Plug kit for mains adapter, singel charger station

1.3 Qseal-free parts and spare parts

1.3.1 Qseal-free, REF CS646

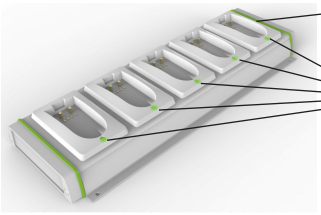
Qseal-free comprises the parts listed below:

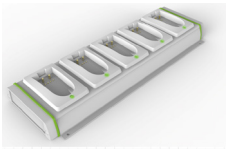
Description	Battery module	Sealing module	Single charger station	Mains adapter, single charger station	Plug kit for mains adapter, single charger station
REF	64650000	64600000	64660000	64661900	64662000

List of all cables and maximum lengths of cables, transducers and other accessories with which the manufacturer claims compliance (cables, accessories used other than those listed may impact emission/immunity):

Part	**Reference**	**Specification**
Mains adapter single charger station	964661900	Input: 100-240 V~50-60 Hz/650 mA Output: 12V ⎓ /2.33A
Plug kit mains adapter single charger station	964662000	
Mains adapter multi charger station	964662100	Input: 100-240V~50-60 Hz, 1.4-0.7A Output: 12V ⎓5.0A, 60W Max
Cable kit mains adapter multi charger station (UK, USA, AUS/NZ, EU)	964662200	

1.3.2 **Accessories** (order separately)





Description	Multi charger station	Mains adapter multi charger station	Cable kit for mains adapter, multi charger station
REF	964661000	964662100	964662200

1.3.3 **Qseal-free spare parts** (user interchangeable parts)

Description	Battery module	Sealing module	Single charger station	Mains adapter, single charger station	Plug kit for mains adapter, single charger station
REF	964650000	964600000	964660000	964661900	964662000

1.4 Symbols/Markings Description

On instrument and labels:

This marking reflects compliance with the Council Directive 93/42/EEC on Medical Devices.

Class II mains adapter: double insulation during charging.

Mains adapter UL recognised component for Canada and U.S.A.

Symbol for “CATALOGUE NUMBER”.

Symbol for “WARNING”.

Symbol for “CONSULT USER MANUAL”.

Symbol for “SERIAL NUMBER”.

Symbol for “MEDICAL DEVICE”.

Symbol for “KEEP DRY”.

Symbol for “Handle with care / FRAGILE”.

Symbol for “NON-IONIZING RADIATION”.

Symbol for “DATE OF MANUFACTURE”.

Symbol for “MANUFACTURER”.

Symbol for “TEMPERATURE LIMIT”.

Symbol for “RELATIVE HUMIDITY LIMITATIONS”.

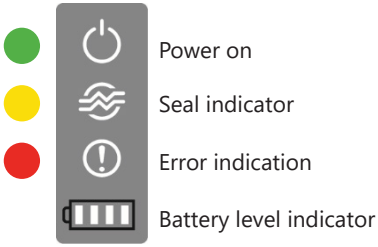
Symbol for “ATMOSPHERIC PRESSURE LIMITATIONS”.

Symbol to indicate information about the battery.

Symbol (WEEE 2002/96/EC) - Do not dispose Product as municipal waste. Collect Product separately. Use collection and return systems available to you. Product brought to EU market after August 13th, 2005.

LED indications

Sealing module



Power on

Seal indicator

Error indication

Battery level indicator

LED Single Charger Table		
LED Indication	**Explanation**	**Recommended action**
Steady green light.	Single charger station connected to mains power.	Single Charger Station ready for use.
Blinking green light.	Charging in progress.	Wait for charging cycle to be completed.
Double green blink followed by pause.	Charging complete.	Battery module ready for use.
Orange light.	Temperature warning or inhibited charging.	Ensure that the environment is not too warm.

2. Installation

This chapter involves unpacking, temperature requirements and installation of the instrument.

2.1 Unpacking and Inspection

1. Visually inspect the cardboard box for damage. Report any damage immediately.
2. Lift the instrument out of the cardboard box and place it on a flat surface.

   The instrument is shipped in one cardboard box that includes:
   1 Sealing module
   1 Battery module
   1 Mains adapter, single charger station
   1 Single charger station
   1 Plug kit
   1 Operator's manual

3. The above list is subject to change, refer to the packing list for accurate description of contents.
   If any parts are missing or if the parts are damaged, report it immediately.
4. Please keep all shipping and packaging materials, as they may be required for later transportation, at least during the warranty time.

2.2 Environmental Requirements

To keep the instrument operating at its best, please observe the following:
• The instrument should be operated in an area free from dust, solvents and acidic vapor.
• Use the instrument in an area free from vibration and with a room temperature of 0 - 35°C (32 - 95°F), and relative humidity 10% - 90%.
• Handle the instrument with care in a clean environment.

2.3 Installation Procedure

Preparing the sealer for use

1. Fit correct mains input plug to the mains adapter.
   The changeable mains plug is available for European continent, UK, USA/Canada and Australia/New Zealand and as IEC standard 320 C8.
2. Attach the mains adapter to the charge station.
3. Plug the mains adapter into the mains. The mains adapter can be connected to mains voltages between 100 and 240 V AC.
4. Place the battery module into the charger station. Make sure that the battery module is properly placed so that the contacts make proper connection.
5. It takes about three hours to charge the battery module completely. Charge the battery to 100% before first use. The battery module is fully loaded when the LED indicator on the charge station shows green double blink followed by pause.
6. Remove the battery module from the charger station. Connect the sealing module to the battery module, ensure that the battery module is correctly inserted. A click will be heard when the 2 modules are connected together.
7. Press the seal button until the LED display lights up. The sealer will perform an automatic calibration by moving the electrode. When the seal light is on, the sealer is ready for use.
   This procedure will be repeated everytime the sealer has been turned OFF.
8. Perform a test seal on an empty or water filled tube to ensure proper operation.

Caution! Only use the enclosed charger station and mains adapter for charging the battery module.

3. Functional Description

This chapter describes how Qseal-free works, where the connectors and the indications are placed on the unit and their functions.

3.1 Description of Sealing

The indication for use of Qseal-free is a need for seal and separation of tubing or bags in blood component sets during blood and plasma donation or other blood component preparation. The target population is determined by the intention of the blood components as determined by the trained medical professionals operating the device. The use of Qseal-free does not limit the initial target population or intended use of the blood components.

The tube to be sealed is placed in the slot of the sealing module between the electrodes. When the user presses the button on the battery module, the tube is pressed together and the sealing procedure will commence automatically. The radio frequency (RF) generator starts and the energy is transferred from the fixed electrode to the tube, which melts to a sterilized welding pattern.

During the whole sealing process the yellow seal indicator on the display of the sealing module is lit. When this light goes out, the sealing is complete and the button may be released. The intelligent sense control in the sealing module detects, controls, and adjusts the necessary sealing activity to give the best sealing quality for the type of tubes that are being used. See section 1.4 for a description of the different LED indications on the sealing module display in case of problems.

3.2 Description of Equipment

Qseal-free consists of a battery module and a sealing module. Below is a short description of each component.

The sealing module consists of an RF-generator with intelligent sense control, the mobile electrode (which can be removed for cleaning). The sealing module uses a little power between sealing.

The battery module consists of the environmental friendly LiIonMn battery pack and ergonomic hand grip with seal button. The charge in the battery module is sufficient for up to 500 seals.

3.3 Checking the battery module

The battery level indication on the sealing module display, is in steps of twenty-five percent. The battery can be recharged at any time or at least when prompted by a blinking battery indicator. The seal function will be blocked if attempted when the level is zero.

Recharging the battery:
Place the battery module into the charger station. Make sure that the battery module is properly placed so that the contacts make proper connection. *See LED indication table*. When the battery is fully charged the charge current is automatically turned off. The charge can be interrupted at any time without damage to the cells, but a full recharge will take less than three hours and is recommended.

Caution! Always check the seals when the battery capacity is low (1 indicator bar or less). *See section 4.2 for sealing pattern.*

Caution! Only use the enclosed charger station and mains adapter for charging battery in the battery module. Alternatively the Multi Charger Station can be used if more that one battery needs to be charged.
When using Multi Charger Station ensure that the power cable is accessible to allow for disconnection from the mains.

Note! To guarantee a long lifetime for the rechargeable battery, please observe the following requirements:
Charge the battery at temperature between 5 and 35°C (40-95°F).

4. Operating Instructions

This chapter describes the use of the instrument.

Caution! Inspect all parts of the instrument for defects before use. Check sealing pattern if sealing module, battery module or complete sealer is dropped.

Caution! Always check the seals when the battery capacity is low (1 indicator bar or less).

Warning! Qseal-free uses radio frequency (RF) energy to generate heat for sealing. Users should be cautious of potential electrical shocks or hazards while handling this sealer. Always keep your fingers away from the electrodes in the slot. Never place any object other than the PVC or EVA tube between the electrodes.

Warning! This instrument emits a low level of electromagnetic (non-ionizing) radiation while sealing. It should not be used near high frequency sensitive electronic equipment. *See table 1 for guidance*.

Warning! Do not allow the front of the sealing module to come in contact with the donor.

Warning! Do not perform a seal within 8 cm (3 in) of needle to preclude an RF burn at the needle entry point.

4.1 Preparation before Use

1. Check that the battery module is correctly connected to the sealing module.
2. If the unit has been turned OFF, an automatic calibration will take place when you press the seal button. *See 2.3 Installation procedure*.
3. Check that there is sufficient battery capacity, see battery level indicator on sealing module display.

4.2 How to Seal Tubes

Note! The tube must be dry on the outside.

1. Put the tube to be sealed down to the bottom of the slot in the sealing module.
2. Check that the tube is placed between the electrodes in the slot.
3. Press the button on the battery module to bring the two electrodes closer together until the seal indicator on the display lights up. The sealing time is normally 1-2 seconds; after a maximum of 5 seconds the RF is turned off.

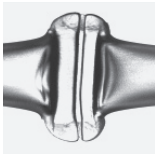
Note! Do not pull the tube and keep the button fully pressed in until the light goes out. If the button is released the sealing process stops.

4. When the light goes out, sealing is finished. Release the button and remove the tubing.
5. The center of the sealed pattern is very thin and pulling both sides will divide the tube into two pieces.
6. Check the tube for leakage.

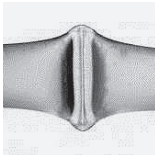
Caution! If you should make two or more seals, they should not be within 1 cm (½ in) of each other, otherwise the resulting pressure in the tube may cause microscopic cracks and holes in the seals.

Caution! In case of sealer malfunction (intermittent operation, poor seal quality, the sealing time seems too long or too short) contact your local Conroy Medical representative for assistance.

Caution! Periodically check the pattern of the sealing visually (see picture below).



Good sealing pattern



Bad sealing pattern

4.3 If the Sealer Doesn´t Start

The Sealer has several safety functions. Before sealing, these functions control and identify whether it is possible to seal the tube. The table below covers the common probable causes for problems and suggests some recommended actions.

Probable cause	Recommended action
Wet tube	Dry the tube and try again.
Tiny arcs between the electrodes	Dry the electrodes and try again.
Wet or dirty electrodes	Clean and dry the electrodes.
Low/no capacity in battery (1 bar indication blinking)	Check/charge battery.
Over heated (error indication red blink on display)	Let the sealing module cool down.
No seals	Check that the battery module is correctly connected to the sealing module.

If the sealer still doesn't start, see chapter 6 for further information.

5. Cleaning

This chapter gives information on the cleaning (procedure, frequency) of the battery module and sealing module.
The sealer requires minimal maintenance for efficient operation.
Follow the cleaning procedure below.

Warning! For you own safety always disconnect the sealing module from the battery module.

Warning! Blood and blood products must be treated as potentially infectious at all times. In the event of blood spillages, appropriate protective clothing should be worn during cleanup procedures.

After removing residual biological material, surfaces which have been in contact with blood or components must be disinfected using a chemical agent considered to be "sterilizing" (isopropanol 70%,....). Alternatively, a freshly prepared solution of diluted sodium hypochlorite (household bleach) may be used to disinfect surfaces which will not be harmed by the solution. Diluted solutions of 1 part bleach to 10 parts water may be used.

Regardless of the "sterilant" or disinfection solution used, remember to remove any residue to ensure that surfaces of the equipment are not subject to corrosion or discoloration. Discard all materials in contact with blood according to institutional policies regarding disposal of biohazardous materials.

Caution! Do not disinfect or sterilize any part of the Sealer through autoclave, or with ethylene oxide gas. To do so will render the Sealer unusable and invalidate the warranty.
Do not use chemical or abrasive cleaners such as acetone, ammonia or similar.
Do not use sharp edged tools for cleaning, which could damage the finish of the units.

5.1 Battery module

Cleaning may be required as a result of spilled drops of blood or when required after inspection.

If spillage occurs, the unit must immediately be removed from service and cleaned completely before resuming use.

Use a soft lint-free tissue, moistened with a mild detergent to clean the outside of the battery module.

Caution! Do not, under any circumstances, submerge the battery module in any kind of liquid. This will damage the battery module and void the warranty.

5.2 Sealing module

Cleaning may be required as a result of spilled drops of blood or when required after inspection.

Clean the sealing module and both electrodes with a soft lintfree cloth moistened with mild detergent. Dry carefully and ensure that the electrodes are completely dry to prevent sparks.

After cleaning, inspect the electrodes for any mechanical damage or wear out.
Do not use damaged part.

Note! Some sealing tests are recommended before resuming use. Compare the pattern against picture in Section 4.2.

Caution! Do not submerge the units in liquid. Intruding liquid will cause malfunction, tiny arcs and void the warranty.

6. Troubleshooting

Maintenance performed by the user is limited to changing battery module, sealing module, charger station and mains adapter. The following information covers common problems and offers suggested solutions.

6.1 Battery module

Problem	Probable cause	Recommended action
Charge level LED's doesn't light.	No voltage.	Charge battery module.
	Battery too low voltage.	Charge battery for 48 hours.
	Other cause.	Contact your local C.M. representative.
Charge level LED's lights green but when trigger is pressed the seal lamp doesn't light.	No connection.	Check cable.
	Sealing module defective.	Change sealing module or contact your local C.M. representative.
	Charge level indicator wrong.	Charge battery for 3 hours.
	Battery module defective.	Contact your local C.M. representative.
	Other cause.	Contact your local C.M. representative.

6.2 Sealing module

Problem	Probable cause	Recommended action
The sealing doesn't start.	Wet electrodes.	Dry the electrodes, see chapter 5.2.
	Dirty electrodes.	Clean the electrodes, see chapter 5.2
	Wet tube.	Dry the tube and electrodes, try again.
	Tiny arcs between the electrodes.	Dry the electrodes and try again.
	No "click" when button is pushed.	Change battery module.
	Sealing module defective.	Change sealing module or contact your local C.M. representative.
	Battery not charged/low charge.	Charge battery for 3 hours.
	Other cause.	Contact your local C.M. representative.
Bad sealing.	Low battery charge.	Check battery module.
	Wet electrodes.	Dry the electrodes and try again.
	Dirty electrodes.	Clean the electrodes, see chapter 5.2.
	Sealing module defective.	Change sealing module or contact your local C.M. representative.
	Other cause.	Contact your local C.M. representative.
Hard to divide tube after seal.	Wet electrodes.	Dry the electrodes and try again.
	Dirty electrodes.	Clean the electrodes, see chapter 5.2.
	Rim on moving electrode damaged.	Contact your local C.M. representative.
	Other cause.	
Intermittent sealing. Does not start.	Sealing module defective.	Change sealing module or contact your local C.M. representative.
	Battery module defective.	Contact your local C.M. representative.
Seal lamp still alight after seal button has been released.	Seal switch is broken.	Contact your local C.M. representative.
	Sealing module defective.	Change sealing module or contact your local C.M. representative.
Seal lamp doesn't light.	Sealing module defective.	Change sealing module or Contact your local C.M. representative.
Seal lamp flickers.	Other cause.	Contact your local C.M. representative.

Error Indication Table		
Error Indication	**Probable cause**	**Recommended action**
1 blink	Display/ Power error.	Restart the sealing unit and re-try. If problem remains change sealing module or contact your local C.M. representative.
2 blink	Temperature error.	Wait until blinking stops. Restart the sealing unit and re-try. If problem remains change sealing module or contact your local C.M. representative.
3 blink	Communication error.	Change battery module.
4 blink	Motor error.	Restart the sealing unit and re-try. If problem remains change sealing module or contact your local C.M. representative.
5 blink	Calibration error.	

7. Warranty and Service

Information on the warranty and the service provided by Conroy Medical is listed below:

7.1 Warranty

Conroy Medical guarantees that the equipment shall be free from defects in material and workmanship when delivered to the original purchaser. Conroy Medical´s sole obligation shall be limited to repair or replacement, at Conroy Medical´s option and expense, of the defective part or unit for a period of two (2) years following the date of initial delivery to original purchaser.
The warranty extends only to the original purchaser and is not assignable or transferable, and shall not apply to auxiliary equipment, or disposable accessories.

Conroy Medical guarantees that the equipment is fit for the purposes and indications described in the labelling when used in accordance with the directions for use. Unless the equipment is used in accordance with such instructions, this warranty is void and of no effect. No other expressed or implied warranty exists, including any warranty of merchantability or appropriateness for a particular purpose. Conroy Medical's sole obligation and original purchaser's exclusive remedy for breach of warranty shall be limited to repair or replacement at Conroy Medical´s option. Conroy Medical shall not be liable for proximate, incidental or consequential damages. Modifications, alterations, recalibrations or abuse, and service by other than a Conroy Medical authorized representative will void the warranty.

7.2 Service

Service under warranty period

While under Conroy Medical warranty, the instrument must not be opened by unauthorized personnel. **Contact your local Sales Office or approved repair vendor** for service and repair information for all Qseal-free instruments.
Shipping costs for all units returned to Conroy Medical or Conroy Medical´s authorised representative shall be paid by the original purchaser. The unit must be packed in its original box or in another box that will provide adequate protection during shipment. To ensure prompt return, a Conroy Medical representative must be notified before shipping any unit for repair.

When contacting Conroy Medical representative, please be prepared to provide part number and serial number of the unit. A service request number will be issued and should accompany all communications. A brief written description of the problem should be attached to the instrument when it is returned for service.
Conroy Medical will not be responsible for unauthorized returns or for units damaged in shipment due to improper packing.

Service after warranty period

After Conroy Medical warranty period, the Qseal-free will continue to be serviced by Conroy Medical. If servicing of the device is performed by the original purchaser´s technical department, Conroy Medical will make available on request the service manual including non-confidential information (component part lists, descriptions, calibration instructions), periodic preventive maintenance guide, and any other non-confidential information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by Conroy Medical as repairable.

Preventive Inspection and Maintenance

At least every second year, the Qseal-free must be fully inspected:
- either by the qualified service organization of the original purchaser,
- or by Conroy Medical or Conroy Medical´s authorized representative.

Interchangeable Parts Replacement (Maintenance performed by user)

Maintenance is limited to changing the battery module, sealing module, charger station and mains adapter. The information in chapter 6 (Troubleshooting) covers common problems and offers suggested solutions.

7.3 Product Disposal

Product Disposal

For disposal of Qseal-free, or parts thereof, (including accessories) at the end of the calculated life cycle of 7 years, please ensure the following:

- Do not dispose Qseal-free as unsorted municipal waste.
- Collect the Qseal-free separately.
- Use the collection and return systems available to you.

For more information on return, recovery or recycling of Qseal-free, please contact your local Conroy Medical representative.

8. Local Sale Office

EU DECLARATION OF CONFORMITY

Legal Manufacturer:	Conroy Medical AB
Legal Manufacturer Address:	Haesthagsvaegen 14A SE-194 52 Upplands Vaesby Sweden
SRN (Single Registration Number):	SE – MF – 000027430
Basic UDI-DI:	735011599100A9
Name of the Device:	Qseal-free
Product Code:	CS646
Intended purpose:	Intended for sealing tubes and bags in blood component sets.
Classification and Rule:	Class I, according to Rule 1 in Annex VIII of Regulation (EU) 2017/745
Main standard:	IEC 60601-1:2005 + AMD1:2012 + AMD2:2020

CE

We hereby declare that the medical device specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical device and Directive 2011/65/EU (RoHS). This declaration is supported by the quality system approval to ISO 13485 issued by Intertek IMNB. This declaration of conformity is issued under the sole responsibility of Conroy Medical AB.

Upplands Vaesby, 2024-10-07
Place and date

Nicklas Lundman, CEO

Operator´s Manual
CS646 Cordless Battery Sealer

CONROY Medical

conroymedical.com